

Kentucky Department for Medicaid Services

Drug Review Options

The following chart lists the agenda items scheduled and the options submitted for review at the November 20, 2008, meeting of the Pharmacy and Therapeutics Advisory Committee

Item	Options for Consideration
<u>Agents for Pulmonary Hypertension</u>	<ol style="list-style-type: none"> 1. DMS to select preferred agent (s) based upon economic evaluation; however, at least one agent should be preferred. 2. Sildenafil will be subject to prior authorization criteria to ensure it is being used for PAH. 3. Agents not selected as preferred will be considered non-preferred and will require Prior Authorization. 4. For any agent not selected as preferred, DMS to allow continuation of therapy if there is a paid claim in the past 90 day. 5. For any new chemical entity in the Oral Agents for Pulmonary Hypertension class, require a PA until reviewed by the P&T Advisory Committee.
<u>Clinical Criteria for Revatio™</u>	Revatio™ will be authorized for the treatment of Pulmonary Arterial Hypertension ONLY .
<u>Oral 5-ASA Derivatives</u>	<ol style="list-style-type: none"> 1. DMS to select preferred agent (s) based upon economic evaluation; however, at least two unique chemical entities should be preferred. 2. Agents not selected as preferred will be considered non-preferred and will require Prior Authorization. 3. For any new chemical entity in the 5-ASA Derivatives, Oral Preparations class, require a PA and until reviewed by the P&T Advisory Committee.
<u>Nitroimidazoles</u>	<ol style="list-style-type: none"> 1. DMS to select preferred agent (s) based upon economic evaluation; however, at least one nitroimidazole should be preferred. 2. Agents not selected as preferred will be considered non-preferred and will require Prior Authorization. 3. For any new chemical entity in the nitroimidazole class, require a PA until reviewed by the P&T Advisory Committee.
<u>New Drugs to Market: Stavzor™</u>	Based on the Committee's previous recommendations for this drug class, place this product preferred in the PDL category titled Anticonvulsants, First Generation.
<u>New Drugs to Market: Alvesco®</u>	Place this product non preferred in the PDL category titled Corticosteroids, Inhaled with quantity limits sufficient to allow for the maximum recommended daily dose.
<u>New Drugs to Market: Nplate™</u>	Allow this product to pay unrestricted as Platelet Proliferation Stimulants are not listed on the KY PDL.
<u>New Drugs to Market: Zamicet™</u>	Place this product non preferred in the PDL category titled Analgesics: Short-Acting with the same duration edit as other hydrocodone/APAP combination products.
<u>New Drugs to Market: Durezol™</u>	Place this product non preferred in the PDL category titled Ophthalmic Anti-Inflammatory Steroids.
<u>New Drugs to Market: Keppra® XR</u>	Based on the committee's previous recommendation for this class, place this product preferred in the PDL category titled Anticonvulsants: Second Generation.
<u>New Drugs to Market: venlafaxine ER</u>	Place this product non preferred in the PDL category titled Antidepressants: SNRIs.

Item	Options for Consideration
<u>Topical Agents for Psoriasis</u>	<ol style="list-style-type: none"> 1. DMS to select preferred agent (s) based upon economic evaluation; however, at least one agent should be preferred. 2. Agents not selected as preferred will be considered non-preferred and will require Prior Authorization. 3. DMS to allow continuation of therapy for agents selected as non-preferred for patients who have a history within the last 180 days. 4. For any new chemical entity in the Topical Agents for Psoriasis, require a PA until reviewed by the P&T Advisory Committee.
<u>Progestins for Cachexia</u>	<ol style="list-style-type: none"> 1. DMS to select preferred agent (s) based upon economic evaluation; however, Megace ES® must be preferred. 2. Agents not selected as preferred will be considered non-preferred and will require Prior Authorization. 3. For any new chemical entity in the Progestins for Cachexia class, require a PA until reviewed by the P&T Advisory Committee.
<u>Direct Renin Inhibitors</u>	<ol style="list-style-type: none"> 1. DMS to select preferred agent (s) based upon economic evaluation. 2. Require a Step Therapy Edit for any two Antihypertensive agents in the past 180 days. 3. Agents not selected as preferred will be considered non-preferred and will require Prior Authorization. 4. DMS to allow continuation of therapy for patients who have a history within the last 90 days. 5. For any new chemical entity in the Direct Renin Inhibitor Class, require a PA until reviewed by the P&T Advisory Committee.
<u>Direct Renin Inhibitors Clinical Criteria</u>	Tekturna® or Tekturna HCT® will be automatically approved if any two antihypertensive products are located in history within the past 180 days.
<u>Selective Norepinephrine Reuptake Inhibitors (SNRIs)</u>	<ol style="list-style-type: none"> 1. DMS to select preferred agent(s) based upon economic evaluation; however, at least one SNRI should be preferred. 2. Agents not selected as preferred will be considered non-preferred and will require Prior Authorization. 3. Any new chemical entity in the SNRI class will require a PA until reviewed by the P&T Advisory Committee. 4. If duloxetine is selected as a non preferred agent, it should have additional criteria to allow for its use in fibromyalgia and diabetic peripheral neuropathic pain unless there are other SNRIs that gain those FDA-approved indications in the future.
<u>Cymbalta® Clinical Criteria</u>	<p>Cymbalta® will be authorized for the following diagnoses:</p> <ul style="list-style-type: none"> • Depression/Major Depressive Disorder/Generalized Anxiety Disorder/Social Anxiety Disorder/Panic Disorder: Approval after trial and failure of intolerance or contraindication to one preferred SNRI. • Diabetic peripheral neuropathic pain • Fibromyalgia: Approval will be granted after trial and failure of or intolerance or contraindication to: <ul style="list-style-type: none"> ○ A tricyclic antidepressant or muscle relaxant AND ○ At least one of the following: <ul style="list-style-type: none"> ▪ SSRI ▪ A preferred SNRI ▪ Anticonvulsant: pregabalin or gabapentin

Item	Options for Consideration
<u>Hematopoietic Agents</u>	<ol style="list-style-type: none"> 1. DMS to select preferred agent (s) based upon economic evaluation. 2. All hematopoietic agents will require Prior Authorization. 3. For any agent not selected as preferred, DMS to allow continuation of therapy if there is a paid claim in the past 90 day. 4. For any new chemical entity in the hematopoietic class, require a PA until reviewed by the PTAC.
<u>Hematopoietic Agents Clinical Criteria</u>	<p>Erythropoiesis stimulating agents will be approved for recipients meeting one of the following criteria:</p> <ul style="list-style-type: none"> • The patient has a hemoglobin of less than 12 g/dL AND one of the following diagnoses: <ul style="list-style-type: none"> ○ Anemia associated with chronic renal failure (patients may be on dialysis or pre-dialysis) OR anemia associated with kidney transplantation ○ Treatment of chemotherapy induced anemia for non-myeloid malignancies ○ Drug-induced anemia (examples, not all inclusive: Retrovir® or Combivir® or ribavirin) ○ Autologous blood donations by patients scheduled to undergo nonvascular surgery; OR, • The patient is an infant (up to 6 months old) with a diagnosis of Anemia of Prematurity (no lab work required-allow 8 weeks of therapy).
<u>COPD Anticholinergics</u>	<ol style="list-style-type: none"> 1. DMS to select preferred agent (s) based upon economic evaluation; however, tiotropium must be a preferred agent. 2. Agents not selected as preferred based on economic evaluation will require PA. 3. Continue quantity limits based on maximum recommended dose. 4. For any new chemical entity in the Inhaled Anticholinergics class, require a PA until reviewed by the PTAC.
<u>Insulins</u>	<ol style="list-style-type: none"> 1. DMS to prefer one brand of human insulin per class (bolus, basal, premixed, rapid-acting, intermediate-acting and long-acting) based upon economic evaluation. 2. DMS to require PA for pen delivery systems for patients unable to manipulate vials/syringes (eyesight, dexterity, comprehension). 3. For any new chemical entity in the insulin class, require a PA until reviewed by the P & T Advisory Committee.
<u>Insulin Pen Clinical Criteria</u>	<p>Insulin pens should be reserved for patients <u>or active care-givers</u> that are unable to manipulate vials/syringes due to issues related to poor eyesight, dexterity, or comprehension.</p>
<u>Bisphosphonates</u>	<ol style="list-style-type: none"> 1. DMS to select preferred agent (s) based upon economic evaluation; however, at least one bisphosphonate should be preferred. 2. Agents not selected as preferred based on economic evaluation will require PA. 3. Continue quantity limits based on maximum recommended dose. 4. For any new chemical entity in the Bisphosphonate class, require a PA until reviewed by the PTAC.

Item	Options for Consideration
<p><u>Lyrica® Clinical Criteria</u></p>	<p>COVERED DIAGNOSES:</p> <ul style="list-style-type: none"> • Diabetic Peripheral Neuropathy (DPN) • Postherpetic Neuralgia (PHN) <ul style="list-style-type: none"> ○ Adequate trial and failure of OR intolerance OR contraindication to at least one of these first-line agents <ul style="list-style-type: none"> • Tricyclic antidepressant (TCAs) • Anticonvulsant: gabapentin • Topical: Lidocaine 5% patch • Adjunct for partial onset seizure disorder via an ICD-9 override • Fibromyalgia <ul style="list-style-type: none"> ○ Adequate trial and failure of OR intolerance OR contraindication to all of the first-line agents below: <ul style="list-style-type: none"> ▪ Tricyclic antidepressant (TCAs) OR muscle relaxant AND ▪ At least one of the following: <ul style="list-style-type: none"> • SSRI • SNRI • Anticonvulsant: gabapentin